

In re Application of:

J. Leng  
Application No.: 09/559,874  
Filed: April 25, 2000  
Page 7

PATENT  
Attorney Docket No.: CHEM1100

REMARKS

**A. Regarding the Amendments**

Claims 1, 18, 31 and 63 have been amended, as set forth above in the Listing of the Claims. As amended, the claims are supported by the specification and the original claims. No claims have been cancelled by the present amendment. Thus, upon entry of this Supplemental Preliminary Amendment, claims 1-47 and 63-73 will be pending.

It is acknowledged that the Final Office Action mailed August 29, 2002 has been withdrawn. Applicant's present response is therefore further in response to the Final Office Action mailed October 31, 2001 (Paper No. 9) and the Advisory Action (Paper No. 14) mailed June 4, 2003, and further considers the telephonic interview between Examiner Stephen Rawlings, Examiner Caputa and Applicant's representatives on May 13, 2003 and is submitted as an addition to the preliminary amendment filed August 15, 2002. Accordingly, consideration by the Examiner of all claim amendments and arguments contained herein is respectfully requested in addition to consideration by the Examiner of all arguments contained in the preliminary amendment filed August 15, 2002.

**B. Rejection Under 35 U.S.C. §112, first paragraph**

Claims 1 to 47 and 63 to 68 are rejected as allegedly not enabled under 35 U.S.C. §112, first paragraph. The rejection is respectfully traversed.

The Examiner has alleged, most recently in Paper No. 14, that the claims are allegedly not enabled as the application has not established a strict correlation between bioluminescence and cell proliferation. Applicants respectfully submit that the application does provide such a correlation, and further in support of this position, Applicant has provided a Declaration under §1.132 with the present Supplemental Preliminary Amendment stating that there is a direct correlation between bioluminescence and cell viability. In this Declaration, Applicant has declared that he has performed experiments according to the teachings of the art (MTS assay) and

In re Application of:

J. Leng  
Application No.: 09/559,874  
Filed: April 25, 2000  
Page 8

PATENT  
Attorney Docket No.: CHEM1100

the teachings of the application (Luciferase assay). Exhibit A to the declaration explicitly sets forth the protocol of each assay performed. The results of these experiments demonstrate that, as measured by the conventional MTS assay, proliferation was present at both concentrations of 12500 cells/well and 195 cells/well in the absence of Cytochalasin D and that proliferation was notably hindered in the presence of Cytochalasin D at both concentrations. The Luciferase assay of the same concentrations, also in the presence and absence of Cytochalasin D detects similar proliferation and inhibition levels. Accordingly, it is apparent from the results that the Luciferase assay detects proliferation in cells in the absence of a toxic agent and detects inhibited proliferation in the presence of a toxic agent and therefore there is a detectable correlation between bioluminescence and cell viability and cell sensitivity to a toxic agent. Therefore, it is respectfully submitted that the methods of the invention are enabled for methods of measuring proliferation comprising measuring luminescence produced by intact cells.

Accordingly, Applicant respectfully traverses the rejection of claims 1-47 and 63-68 as allegedly non enabled under 35 U.S.C. §112, first paragraph. As set forth above and in the Preliminary Amendment submitted August 15, 2002, one of skill in the art would be able to practice the present invention. Therefore, claims 1-47 and 63-68 meet the enablement requirement of 35 U.S.C. §112, first paragraph. Accordingly, removal of the rejection is requested.

### CONCLUSION

In summary, for the reasons set forth herein, taken in combination with the reasons set forth in the Preliminary Amendment submitted August 15, 2002, Applicants maintain that claims 1-47 and 63-80 clearly and patentably define the invention, respectfully request that the Examiner reconsider the various grounds set forth in the Office Action, and respectfully request the allowance of the claims which are now pending.

In re Application of:  
J. Leng  
Application No.: 09/559,874  
Filed: April 25, 2000  
Page 9

PATENT  
Attorney Docket No.: CHEM1100

If the Examiner would like to discuss any of the issues raised in the Office Action, Applicant's representative can be reached at (858) 677-1456. No fee is deemed necessary in connection with the filing of this response. However, if any fee is deemed necessary, the Commissioner is authorized to charge (or apply any credits to) Deposit Account 50-1355.

Respectfully submitted,

Date: July 14, 2003

  
Kelly K. Reynolds, J.D.  
Registration No. 51,154  
Telephone: (858) 638-6724  
Facsimile: (858) 677-1465

GRAY CARY WARE & FREIDENRICH LLP  
4365 Executive Drive, Suite 1100  
San Diego, California 92121-2133  
USPTO Customer Number 28213

Gray Cary\GT\6356438.1  
105175-159906